K121683

JUL 5 2012

510(k) Summary

Submitted By:
CoAlign Innovations
150 North Hill Drive, Suite 1
Brisbane, CA 94005

Establishment Registration Number: 10030843

Contact Person: (Submission Prepared by)
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Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
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Date Prepared: July 3, 2012

Device Trade Name: AccuLIF Cage

Manufacturer:
CoAlign Innovations, Inc.
150 North Hill Drive, Suite 1
Brisbane, CA 94005

Common Name: Intervertebral body fusion device

Classification: 21 CFR §888.3080

Class: II

Product Code: MAX

Device Description:

The AccuLIF TL Cage acts as a spacer to maintain proper intervertebral spacing and angulation following discectomy. The AccuLIF TL Cage is manufactured from TI6Al4V ELI) as per ASTM F136-08, Stainless Steel (316 LVM) as per ASTM F138-08, and Silicone Rubber (MED-4870). The device is inserted in unexpanded state with an articulating delivery handle and expanded in-situ to the required height via 2 hydraulic cylinder and piston arrangement using a hydraulic system comprising disposable flexible expansion tubing set and inflation syringe. The device locks in 1mm increments as it expands. The AccuLIF Cage comes in 6 to 9mm, 8 to 12mm and 10 to 16mm sizes. Each size also comes in an 11mm x 34mm footprint and a 13mm x 34mm footprint. The device has fixation ridges on the top and bottom surface. It also has a graft opening window which extends from the bottom surface to the top surface. The device has a

proximal boss which has a threaded connection port for connecting to the inserter and a fluid port for transporting the expansion fluid.

In addition, the AccuLIF TL Cage System includes distractor trials to aid in distracting the disc space and in selecting the appropriate size cage to use in the surgical procedure. The set also contains a variety of other instruments to aid in the implantation of the cages.

Indications For Use:

The CoAlign Innovations AccuLIF TL Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

The CoAlign Innovations AccuLIF TL Cage is always to be used with supplemental internal spinal fixation. Additionally, the CoAlign Innovations AccuLIF TL Cage is to be used with autogenous bone graft.

Identification of Predicates

- AccuLIF® TL Cage (K113465)
- CRESCENT® Spinal System Titanium (K110543)

Summary of Technological Characteristics

AccuLIF® TL Cages are expandable spacers made from Titanium-6AL-4V ELI alloy that conforms to ASTM F136. There have been no changes to the implants and subject and predicate cages have identical technological characteristics. The addition of distractor trials to the system does not raise any new issues of safety and effectiveness.

Discussion of Testing:

The only change to the system was to add additional Class II instruments to the AccuLIF® Cage system, which was validated through cadaver testing. No bench testing was required.

Conclusions:

The subject and predicate devices share the same indications for use, design, function, and materials of manufacture. The non-clinical test results demonstrate that the addition of the distractor trial instruments to the system do not impact device safety and effectiveness or performance as compared to the predicates. The AccuLIF® TL Cages were shown to be substantially equivalent to the AccuLIF® TL Cage (K113465) and CRESCENT® Spinal System Titanium (K110543).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Coalign Innovations, Incorporated
% Musculoskeletal Clinical & Regulatory Advisers, LLC
Mr. Justin Eggleton
1331 H Street Northwest
Washington, District of Columbia 20005

JUL 5 2012

Re: K121683
Trade/Device Name: AccuLIF TL Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: June 06, 2012
Received: June 07, 2012

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): _____

Device Name: AccuLIF TL Cages

The CoAlign Innovations AccuLIF TL Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

The CoAlign Innovations AccuLIF TL Cage is always to be used with supplemental internal spinal fixation. Additionally, the CoAlign Innovations AccuLIF TL Cage is to be used with autogenous bone graft.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121683